

K131753

NOV 14 2013

510(K) SUMMARY
Meridian

Contact: Donna Marie Hartnett

Company: Ardent, Inc. 175 Pineview Drive, Amherst, NY 14228
(716) 691-0010

Date Prepared: June 13, 2013

Proprietary Name: Meridian

Classification Name: Material, Tooth Shade, Resin (872.3690)

Predicate Devices: Tetric EvoCeram (K042819)

Device Description: Meridian is a light curing universal dental composite material of the latest nanohybrid type having an optimized chemical composition.

The predicate device to which Meridian has been compared is Tetric EvoCeram (K042819). For this application, Tetric EvoCeram has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that Meridian is substantially equivalent to the predicate device.

Intended Use: Meridian is a direct filling material for restoration of Class I to V cavities and for restoration of deciduous teeth.

Technological Characteristics: The device design, i.e. delivery form, and intended use of Meridian and the predicate device are the same. The composition of the subject device has been modified from the predicate, however, there are no ingredients in the subject device which pose any new issues of safety and effectiveness.

Guidance Document: The submission was prepared in accordance with FDA Guidance document entitled Dental Composite Resin Devices – Premarket Notification (510K) Submissions dated October 26, 2005.

Testing Summary: The device was tested in accordance with ISO 4049:2009 for Polymer based dental restorative materials for Water Absorption, Water solubility, Radiopacity, Flexural Strength, Depth of Cure, Modulus of Elasticity, and Compressive Strength and the results from testing demonstrates that Meridian is substantially equivalent to the predicate device. Biocompatibility testing and evaluation was also carried out according to ISO 10993.

Conclusion: Meridian is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 14, 2013

AB Ardent
C/O Ms. Donna Marie Hartnett
Director Quality Assurance/Regulatory Affairs
175 Pineview Drive
AMHERST NY 14228

Re: K131753
Trade/Device Name: MERIDIAN
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 3, 2013
Received: September 5, 2013

Dear Ms Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131753

Device Name: MERIDIAN

Indications For Use:

Meridian is a direct filling material for restoration of Class I to V cavities and for restoration of deciduous teeth.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Andrew I. Steen -S

2013.11.14 08:21:40 -05'00'